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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,941	08/28/2001	Atsushi Sogabe	211352	6205

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 11/01/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,941

Applicant(s)

SOGABE ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 6.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The amendment filed August 13, 2002 amending claims 24, 25, 33 and 35-37 has been entered.

The substitute Declaration filed August 13, 2002 stating that all errors being corrected were made without any deceptive intent has been entered.

Claims 24-42 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as
containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 33 and 35-37 have been amended to indicate that Optimum temperature is determined "at a pH of about 6-8". Applicants indicated support for the amendment at column 6, lines 47-49, and column 7, lines 12-19 of the specification (Remarks, page 4). At column 6, lines 47-49, the specification states that "the reagent for determination of creatine or creatinine of the present invention is generally used with a buffer having

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a pH of about 6-8". This does not mean that temperature optimum is within this range of pH. Temperature optimum has been measured only at pH 7.5 (column 7, lines 1-24). Thus there is no indication that Optimum temperature sustained within the range of pH 6-8 instead of pH 7.5 was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 24-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated from the Office action mailed February 12, 2002.

The claims have been amended to insert preamble "[A creatine amidinohydrolase] encoded by a nucleic acid sequences obtained by mutation of (a) the nucleic acid sequence of SEQ ID NO:2 or (b) a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:1". Because the number of mutation is not limited such preamble is not considered a limitation and is of no significance to claim construction.

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Claims 24-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a creatine amidinohydrolase having K_m for creatine of 3-10 mM obtained by mutation of a DNA encoding a wild type creatine amidinohydrolase from *Alcaligenes faecalis* (FERM P-14237, SEQ ID NOs:1-2), does not reasonably provide enablement for a creatine amidinohydrolase with molecular weight of 43 kD having K_m for creatine of 3-10.0 mM and some other characteristics defined by a range, said enzyme having any structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

This rejection is reiterated from the Office action mailed February 12, 2002.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 29, 31 and 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the range of various properties. These properties depend on at least pH, temperature and buffer.

"pH stability" is unclear because the amount of activity required to be deemed "stable" is not defined.

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"Heat stability", the phrase "not more than about 50° C" is confusing. It does not define the amount of activity, and therefore, an enzyme stable at 45° C, for example, meets said limitation as well as an enzyme retaining 90% activity at 50° C. Also the range is open ended rendering the metes and bounds of the claims unclear.

Of note, claims 27, 29 and 31 have not been amended to include reference to pH for pH temperature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62-91182.

This rejection is reiterated from the Office action mailed February 12, 2002.

Response to Arguments

Applicant's arguments filed August 13, 2002 have been fully considered but they are not persuasive.

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It is reiterated that claims' preamble introduced by the amendment is not considered a limitation and is of no significance to claim construction because the number of mutation is not limited, *supra*.

With regard to the 112, 1st paragraph, rejections, Applicants argue that "omission of the isoelectric point from the pending claims does not cause those claims, especially as amended, to define subject matter not supported or enabled by the specification" (page 5). Applicants continue to state that "it is impossible to unequivocally derive the amino acid sequence of a protein from its pI value" (ibid). While it is impossible to derive the amino acid sequences, pI allows to derive structural limitations on the entire molecule. Applicants further argue that the differences in the amino acid sequence between different mutants is expected to be 2-3% at most (page 6). This is not persuasive because the claims are not limited to such differences in the sequences. Applicants further compare the pI values for wild-type and three mutants described in the instant application (page 6). This is not persuasive because the claims are not limited to said specific mutants.

With regard to the 112, 2nd paragraph, rejection, the examiner agrees that conditions under which the enzymatic activity is measured and therefore, K_m is determined, is defined at column 6, line 63 through column 7, line 40.

However, the examiner is not agreed with the arguments regarding "pH stability" and "heat stability" because there is no clear definition of these terms in the

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specification or the art. It is unknown whether the residual activity has to be 100% or can be less.

Furthermore, with regard to the thermal stability, the specification indicates thermal stability as "ca 50° C (50 mM potassium phosphate buffer, pH 7.5, 30 min treatment)" for *Alcaligenes faecalis* (FERM P-5374), "ca 40° C (50 mM potassium phosphate buffer, pH 7.5, 30 min treatment)" for *Alcaligenes faecalis* (FERM P-5375), and "ca 40° C (50 mM potassium phosphate buffer, pH 7.5, 30 min treatment)" for *Alcaligenes faecalis* (FERM P-5376) (tables 2, 4 and 6, respectively).

With regard to the 102(b) rejection, Applicants argue that "JP 62-099182 does not disclose a creatine amidinohydrolase with this characteristic [encoded by a nucleic acid sequences obtained by mutation of (a) the nucleic acid sequence of SEQ ID NO:2 or (b) a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:1]" (page 8). This is not persuasive because, as discussed above, this "characteristic" is not considered a limitation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

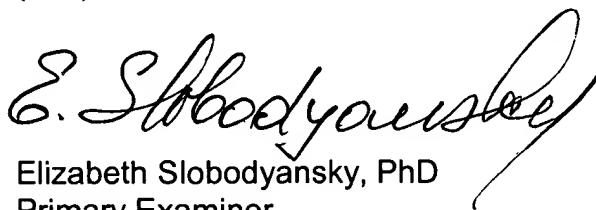
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

October 29, 2002